

ANNEX 2: RESPONSES TO THE CONSULTATION LETTER



WWF's response to the Food Standards Agency's Survey of the migration of bisphenol A from can coatings into food

OVERVIEW and summary

WWF, the global environment network, is the world's largest and most respected independent conservation organisation. We work on a wide range of environmental issues in the UK and around the world, to help conserve endangered species, protect endangered spaces and address global threats to nature. WWF has a global network of experts on toxic chemicals which has been campaigning for several years for the phase out of endocrine disrupting chemicals and other toxic, persistent, and bioaccumulative chemicals.

WWF is an observer at the meetings on the risk assessment of bisphenol A (BPA) undertaken under Regulation 793/93. WWF has made oral presentations and written submissions on a number of technical points. Consequently, WWF is well placed to make comments on the risk assessment of BPA.

- WWF welcomes the fact that the FSA is at last consulting with industry on methods of managing the uncertainties noted by the COT. However due to the uncertainties, WWF considers that it would be appropriate to reduce intakes, on a precautionary basis. Therefore the FSA should consult with industry to find ways of reducing intakes of BPA. The UK food and canning industry has been aware of these concerns for many years and they have been slow in taking steps to find ways of reducing the use of BPA. This consultation is a good start but is well overdue.
- WWF strongly believes that the interests of the consumer should be paramount. The FSA must ensure that margins of safety are adequate, rather than waiting for proof that harm is likely to occur before considering regulatory action. WWF does not believe that the health of consumers is being put first with the FSA's conclusion that levels of the known endocrine disrupting chemical bisphenol A (BPA) in canned foods are "within safety limits" (*'Gender-bending' chemicals found in canned foods*, Daily Mail, Wednesday, May 9).

- WWF maintains that it is vital that all consumers are protected and that worst case scenarios are considered. The FSA's calculation is based on the levels of the chemical that someone would be exposed to through a high daily intake of canned food but only at average contaminant levels. Alarming, we have shown that it is quite feasible for someone to consume more than 10 times the amount of BPA estimated by the FSA. In fact a diet with a very high proportion of canned food, could provide a dose of BPA which exceeds the levels found to produce adverse effects in laboratory animals. Such high intakes are clearly unacceptable.
- The FSA does not take into account, that tinned foods are only one source of exposure to BPA or that BPA is only one of the many endocrine disrupting chemicals to which we are all exposed on a daily basis.
- Worst case intakes should be compared against studies showing low dose effects, where these studies are judged to be credible. Intakes should not be judged in comparison to "out-of-date" tolerable daily intakes, which are in need of revision. It is a matter of some concern, that the dose of 2.6 µg/kg body weight per day, which might arise from a diet with a very high proportion of canned food, exceeds the dose which has been reported to cause effects on prostate weight and time and puberty in mice. In conclusion, WWF considers that these margins of safety are clearly unacceptable, and that in some cases there may be little or no margin of safety.
- WWF considers that there is a need for precautionary action to reduce BPA intakes as far as possible. It should be noted, for example, that in the USA, an expert investigation into the effects of low doses took place in October 2000. The preliminary conclusions of these experts have been reported on the US National Institute of Environmental Health Sciences (NIEHS) internet site.ⁱ With regard to the low dose effects of bisphenol A, this stated,

“ For other compounds, results from different laboratories indicate the presence or absence of low-dose effects (eg. the effect of bisphenol A on prostate weight). Although attempts were made to replicate early results, the Panel concluded that in most cases both the positive and negative study findings are credible and sound within the context of the experimental design. Study design differences (eg. species/strain, animal husbandry, diet, chemical purity, dosing regime, endpoints evaluated, genetic factors, etc.) were identified among laboratories that might account for discrepancies in experimental outcomes.”

These preliminary conclusions have now been removed from the NIEHS web site, after significant pressure was brought to bear by industry, and a letter was sent from the SPI Bisphenol A Global Industry Group to George Lucier at the NIEHS.

- On page 2/16 – the third paragraph states that “For example, BPA migrates from polycarbonate bottles into simulants, but when samples of feed for infants were tested in the UK there was no detectable migration from bottles”. This refers to the study by Mountfort *et al* (1997) which found no migration, but the limit of detection was high, at 30 µg/kg of liquid. A more recent study undertaken by the

Laboratory of the Government Chemists found significant migration of up to 50 µg/l of BPA into milk and juice simulants from polycarbonate babies' feeding bottles that were several months old (Earls *et al.*,2000). WWF therefore considers that the paragraph is unacceptable as it might mislead readers into believing that migration from polycarbonate babies bottles is unlikely to occur. This is clearly not the case. Furthermore, it hides the fact that there is a potential for exposure to BPA from multiple sources.

- WWF strongly believes that a survey of only 62 different canned foods is inadequate to draw conclusions about the potential level of consumer exposure to BPA and consequently takes the view that further research still needs to be done.
- Overall WWF considers that there is sufficient good quality data and enough concern expressed by expert committees, including the Government's own Health and Safety Executive, to support calls for restrictions on the use of BPA and calls on the Government to enact the precautionary principle by putting the health of consumers above the interests of the chemical industry. The Government should give a clear message to the canning and chemical industry that the continued use of BPA in cans is no longer acceptable and should be phased out. This would reassure consumers that the government considers consumer safety to be of greater importance than the interests of the chemical industry.

Matthew Wilkinson 03 July 2001

WWF Response to Questions Specifically raised in the Consultation document

What other measures may be needed to reassure consumers ?

WWF believes that consumers would be reassured if the UK Government demonstrated that it placed concerns about consumer exposure to toxic chemicals above the interests of the chemical industry. The Government could demonstrate this by acting on the precautionary principle to phase out the use of the known endocrine disrupting chemical, BPA, in tin can linings which this survey has shown can lead to consumer exposure.

It would be helpful if industry could provide information on progress on work to find possible alternatives to BPA.

WWF and others have been trying to determine for some time what alternatives exist to the use of BPA in tin can linings. It has been extremely difficult to find this information due to a reluctance for manufacturers and retailers to enter into a constructive dialogue on this subject. WWF welcomes the FSA's call for such information, but is disappointed that it has taken government so long to request, and not even require, industry to provide this crucial information.

Which substances are acceptable to environmentalists and on what scientific basis ?

WWF believes that due to the uncertainties surrounding the potential long-term and irreversible effects of EDCs at low doses, no EDCs should be authorised for use in any product which has the potential to give rise to human or environmental exposure. WWF is also opposed to the use of compounds with highly bioaccumulating or highly persistent properties.

As an overarching principle, WWF believes in the process of substitution whereby the use of any chemical should be evaluated to determine whether its use could be substituted with a chemical of lower toxicity.

What information would consumers welcome about chemical migration from can coatings?

WWF believes in the consumer's 'right to know' about what chemicals are present in all the products they purchase, not just tin cans. Known EDCs should be phased out and all chemical constituents in products should be labelled.

WWF Comments on FSA's Survey

Estimated Intakes

WWF disagrees with the approach taken by the FSA to estimate intakes of BPA, which lead the COT to conclude that BPA intake from this survey would be around 2 orders of magnitude below the TDI. However, the FSA approach only considered **mean** contaminant values whilst it used 97.5 percentile values for daily consumption, as identified in dietary questionnaires. WWF maintains that it is vital that all consumers are protected and that worst case scenarios are considered. This would require the consideration of consumption of foods with levels of contamination greater than the mean. By using contaminant levels identified in the survey, it is shown below how easy it would be for a pregnant woman, for example, weighing 55 kilograms (kg) to be exposed to around 2.6 micrograms (µg) of BPA per kg body weight from canned foods. This far exceeds the 0.36 µg/kg body weight daily intake estimated by the FSA.

Example of potential intake of a pregnant woman:

Lunch

300ml Sainsbury's New Potatoes = 0.048mg/kg = 0.0144mg/300ml = 14.5microgram/tin

200g of Princes ham = 0.42mg/kg = 0.084 mg/200g = 84 microgram per tin

195ml Tesco Baby carrots = 0.042mg/kg = .0082mg/195ml = 8.2 micrograms per tin

Dinner

418g Tesco Chunky chicken and ham = 0.053mg/kg = 0.022 mg/tin = 22 micrograms per tin

+ leftovers from lunch

+ 411g can of Sainsbury's fruit cocktail = 0.038mg/kg = 0.0156mg/tin = 16micrograms per tin

Total intake = approximately 145 micrograms = approximately 2.6 micrograms per kilograms

The need for further work

WWF considers that a survey of only 62 different canned foods is inadequate to draw conclusions about the potential level of consumer exposure to BPA. There were observable trends in the data but there is a need for further research and explanation of some of the findings. For instance, the survey found no detectable levels of BPA leaching into the beverage cans tested. However, this observation is

not commented upon. It is important to know whether there are any reasons for the observed lack of migration, such as:

- Are different resins used to line beverage cans ?
- Is the procedure for processing beverage cans different to that for processing food cans?

From a minimising exposure perspective:

It is important to know how the levels of BPA increase over time. Are the levels higher at the sell-by-date than in new cans, or is all the BPA that is likely to leach present immediately after processing. Does cooking of foods within the can increase the level of leachate in the food?

The survey results indicated higher BPA levels in some overseas products. How well controlled are the canning processes & the quality of resins in different parts of the world?

WWF COMMENTS ON COT's STATEMENT

WWF is an observer at the meetings on the risk assessment of BPA undertaken under Regulation 793/93. WWF has made oral presentations and written submissions on a number of technical points. WWF has also pressed that the output of the risk assessment process should acknowledge the uncertainties that exist due to conflicting data. Consequently, WWF is well placed to make comments on the risk assessment of BPA.

WWF is pleased that the COT acknowledges the uncertainties that exist in the scientific understanding of the potential effects of BPA.

WWF contests the COT's use of the uncertainties in the data to defend the current Tolerable Daily Intake (TDI). In particular, the COT state that they are not considering the experimental results showing low-dose effects in the human risk assessment at the moment because, amongst other reasons, it is not known whether the effects are transient or reversible. Surely, if there is any doubt that the effects are irreversible, then the COT should take a precautionary approach to reduce exposures. Indeed, the UK's Royal Society has acknowledged that "regulations cannot be 'put on hold'" and that "despite the uncertainty, it is prudent to minimise exposure of humans, especially pregnant women, to EDCs"

WWF considers that the COT's conclusion that there is no reason for consumers to change their source of foodstuffs as a result of these findings is misleading. Whilst there may be insufficient evidence currently to advise consumers to change their source of foodstuffs, WWF believes there is sufficient concern to suggest that there should be a change in consumption patterns. If the COT wording is meant to imply that no action is necessary, such a conclusion ignores a large body of research that suggests that action is warranted. In particular, it should be noted that risk assessment currently only considers the likely harm arising from exposure to that single substance, and does not take into account that humans are exposed to many man-made chemicals with endocrine disrupting properties. Experiments have shown that additive effects may occur due to concurrent exposure to many xenobiotics.

In conclusion, WWF considers that there is a sufficient amount of good quality data available and that enough concern has been expressed by expert committees, to support calls for restrictions on the use of BPA in tin can linings.

Toxicology

WWF is concerned that the COT has not taken into account a number of recently published papers, which are outlined below.

Susceptibility

A recent paper by Elsbj and co-workers suggests that humans may be more susceptible to the oestrogenic effects of BPA than rodents which have been used in the risk assessment (Elsby *et al*, 2001).

In utero exposure

Effects on male offspring

vom Saal and co-workers have reported that a dose of 2 micrograms per kilogram body weight, when given orally to pregnant mice on days 11-17, reduced the size of the epididymides and increase the weight of the prostate in male offspring (vom Saal 1998; Nagel *et al*,1997). Similarly, another researcher (Gupta 2000) has confirmed an increase in prostate weight in the male offspring of mice given 50 micrograms per kilogram body weight per day on days 16-18 of pregnancy, as well as effects on anogenital distance and reduced epididymis weight.

Effects on female offspring

Howdeshall and co-workers noted that low doses of BPA may cause an acceleration of the time to vaginal opening (time to puberty). They reported that the female offspring of pregnant mice exposed on days 11 to 17 of gestation to a BPA dose of 2.4 micrograms per kg body weight may reach puberty earlier (Howdeshall *et al*, (1999)). Similarly, Markey *et al* (2001) have shown the effects of low doses of bisphenol A on the mammalian uterus, and have noted that the dose response relationship is non-monotonic. They reported that in immature female mice dosed for three days, the proportion of mice showing vaginal opening was greater after exposure to 100 micrograms / kg BPA, relative to the control animals and those receiving intermediate doses of BPA.

Schonfelder *et al*, (2000) has shown that *in-utero* exposure to BPA, at a dose level of 100 micrograms/kg/day on days 6-21, affects the expression of the oestrogen receptor alpha in the vagina of female rat offspring. This was believed to be responsible for the reported morphological changes in the differentiation, proliferation and cornification of the vagina.

Recent Developments

There have been a number of relevant developments since the view of the COT was published.

Health and Safety Executive Assessment

At the May 30 meeting of the EU Working Group on the Classification and Labelling of Dangerous Substances, the UK Health and Safety Executive (HSE) proposed labelling of BPA as a reproductive toxin. The assessment was based on an interpretation of adverse effects on fertility in traditional high-dose toxicity tests. The tests of relevance were conducted at the Research Triangle Institute (RTI, Research

Triangle Park, North Carolina) for the plastics industry and by the US National Toxicology Program (NTP). Of particular note is the fact that impaired fertility was observed at doses below those demonstrating systemic toxicity such as liver and kidney abnormalities. It was also noted that whilst the mechanism of action of the observed impairment of fertility was not known, it could not be attributed to systemic toxicity. In assessing these studies the HSE concluded that BPA should be labelled as a category two reproductive toxicant, for which serious adverse effects have been demonstrated.

US NTP Peer Review of Low Dose Effects of Endocrine Disruptors

In their Peer Review of Low Dose effects of Endocrine Disruptors, the US National Toxicology Program made several relevant observations and conclusions. They concluded that:

- several studies provide credible evidence for low-dose effects of BPA; these include increased prostate weight in male mice and advanced puberty in female mice after *in utero* exposure to 2 or 20 ng/kg/day, and low-dose effects on uterine growth and serum prolactin levels that occurred in F344 rats exposed to 0.5 mg/kg/day.
- data are insufficient to establish the shape of the dose-response curve for BPA in the low dose region, and the mechanism and biological relevance of reported low dose effects are unclear
- few multigenerational studies have been conducted over expanded dose ranges, and critical endpoints such as cancer have not been evaluated in multi-generational studies.

There was sufficient uncertainty and concern about the current level of understanding of the low dose effects of BPA to recommend:

- additional research to replicate previously reported key low-dose findings,
- further studies to help understand the possible mechanisms and determine the long-term health consequences of low dose effects.

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Abstract in conference proceedings: Bisphenol A: Low dose effects – high dose effects

18th-20th November 2000, Berlin, Germany.

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A physiologically based approach to the study of bisphenol A and other estrogenic chemicals on the size of reproductive organs, daily sperm production, and behaviour.
Toxicol. and Ind. Health **14(1/2)**: 239-260.

¹ Summary Points from Endocrine Disruptors Low-Dose Peer Review

October 10-12 (2000)

(<http://ntp-server.niehs.nih.gov>)

**Food Standards Agency Consultation on
"Migration of bisphenol A from can coatings
into food"**

Response from Friends of the Earth

July 2001

Friends of the Earth inspires solutions to environmental problems which make life better for people.

Friends of the Earth is:

- the UK's most influential national environmental campaigning organisation;
- the most extensive international environmental network in the world, with almost one million supporters across five continents and 68 national organisations worldwide;
- a unique network of campaigning local groups, working in over 200 communities throughout England, Wales and Northern Ireland;
- dependent on individuals for over 90 per cent of its income

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http://www.foe.co.uk/safer_chemicals

Introduction

Friends of the Earth welcomes the opportunity to comment on the Food Standards Agency's approach to bisphenol A. We have been calling for action on this chemical for many years, and have been very concerned at the continuing secrecy surrounding its use. It is clear that the Food Standards Agency needs to pursue its role as consumer champion on this issue, as the industry has proved itself incapable of responding to public concern on this issue.

This brief response sets out Friends of the Earth's approach to this chemical. We believe it is the role of regulators, including the Food Standards Agency, with industry, including supermarkets, to deal with the problems posed by this chemical. Without strong action we would predict that public concern about this chemical, and consequently canned food itself, will increase, as the public understands more about existing and future research on the hazards posed by bisphenol A.

The fundamental principles which guide Friends of the Earth's approach to the regulation and use of chemicals are laid out in the Copenhagen Charter, which is supported by environmental and consumer organisations across Europe, including WWF, the European Environment Bureau and the European Consumers organisation BEUC:

- 1) A full right to know, including which chemicals are present in products.
- 2) A deadline by which all chemicals on the market must have had their safety independently assessed. All uses of a chemical should be approved and should be demonstrated to be safe beyond reasonable doubt.
- 3) A phase-out of persistent or bioaccumulative chemicals.
- 4) A requirement to substitute less safe chemicals with safer alternatives.
- 5) A commitment to stop all releases to the environment of hazardous substances by 2020.

Several of these principles are clearly relevant to the debate on bisphenol a:

- Friends of the Earth considers that consumers, retailers, NGOs and regulators should have a *right to know* which cans contain bisphenol A. Consumers need to be able to make their own choices about their individual exposure to this chemical, retailers need to be able to decide whether to sell it, and regulators need to know where it is used.
- FoE considers that the use of bisphenol A in food contact materials is **not safe beyond reasonable doubt**. Bisphenol A is a proven endocrine disrupter, and many researchers have found endocrine effects at low doses. FoE believes that bisphenol A should be phased out of consumer use as soon as possible, and there should be a longer term aim to phase it out of other uses.
- FoE considers that industry should be obliged to *substitute bisphenol A with safer alternatives*. Effective substitution will only happen if there is complete openness on what can lining systems are available and in development. The industry cannot be left to investigate substitution in secret, where their willingness to move to a substitute will be heavily influenced by issues of profitability and competitive position. It is essential that the regulator and

others are overseeing an open process, based on the public interest and societal need, not short term profitability of individual companies.

The debate on bisphenol A has been a shocking indictment of the secrecy of the canning industry. To give just one example, Friends of the Earth wrote to Heinz in April 2000 asking about their use of bisphenol A in canned food. There was no reply to this letter, so it was chased up in May 2000 - and August 2000. It's now July 2001, and we have so far received no reply from Heinz - hardly the actions of an open, consumer-focussed company. Such behaviour is unlikely to be rewarded if public concern about this chemical increases.

Friends of the Earth also endorses the comments that WWF has made in their response to this consultation.

Answers to individual questions

These questions are largely answered in the 'Introduction' above, which should be read in association with this section.

What measures are needed to reassure consumers over the use of bisphenol A in can linings?

- We consider that bisphenol A should be being phased out of can linings, therefore we do not consider that such reassurance is wise. Clearly any phase out will take time, but this should be an open and honest process. As the FSA well knows, it is better to be honest about concerns and uncertainties, rather than offering false reassurance.

What progress has UK industry made in finding alternatives to bisphenol A?

- Friends of the Earth has no information on this. We hope and expect UK industry to submit such information to the FSA (without claiming commercial confidentiality) to ensure that there can be an open and informed debate on substitutes. If this open process does not occur in this current Food Standards Agency review, then Friends of the Earth will have to consider what options are available to encourage the industry to be open.

What research has been done overseas on bisphenol A migration into canned food and drink?

- Friends of the Earth's information on this is based on searching the published scientific literature, and will therefore not add anything to what the Agency should already be aware of.

What substances are acceptable to environmentalists and on what scientific basis?

- Friends of the Earth believes that an open process should be established to examine the possible substitutes for bisphenol a. We would oppose any substitute that was an endocrine disrupter, or persistent or bioaccumulative.

What information would consumers welcome about chemical migration from can coatings?

- As mentioned earlier, consumers must have a right to know which cans contain bisphenol a and other chemicals. Consumers would also welcome an assurance that efforts are being expended to ensure that the safest possible materials are used in can linings.

4 July 2001

FSA CONSULTATION: MIGRATION OF BISPHENOL A FROM CAN COATINGS INTO FOOD

FDF COMMENTS

General Comments

In preparing our response to this consultation, FDF has liaised with the Metal Packaging Manufacturers Association and endorses their response to the four questions posed by the FSA.

Specific comments on the four questions posed.

- *What other measures may be needed to reassure consumers?*

Food safety is an absolute priority for the food and drink manufacturing industry which will continue to work closely with suppliers of metal packaging to ensure that food and drink products are safe, affordable, enjoyable and nutritious.

The recent FSA survey estimated average intake levels for the daily consumption of foods that were tested. These values are considerably less than the tolerable daily intake of Bisphenol A set out by the EU Scientific Committee on food. In fact FDF has calculated that even based on the upper value of BPA detected of 0.07 mg/kg (leaving aside the one very high result detected in one sample where separate action has already been taken by the brand owner to change the lacquer system) an average adult would have to eat over two thirds of its body weight in canned food every day to reach the TDI. Notwithstanding this, food and drink manufacturers will continue to work with the supply industry to encourage further measure that will reduce the potential for migration of Bisphenol A into foods.

FDF would like to advocate the need for accurate and balanced media reporting of the issue based on the assessment recently made by the COT as a further measure to reassure consumers, in particular the most recent studies on animals supporting a no observable adverse effect level on fertility of at least 100,000 greater than the current exposure from canned foods.

- *It would be helpful if industry could provide information on progress in this work, for example possible alternatives to Bisphenol A*

FDF strongly believes that the safety and quality of food and drink products is a paramount consideration and one that cannot be compromised by making an arbitrary change to an alternative packaging systems that will not deliver the same level of performance and protection of the contents. The lacquer systems used for food cans are based on extensive testing and most have been in commercial use for many years. Food manufacturers therefore have

a large amount of data on performance of these lacquers in terms of their role in preserving the chemical and microbiological safety of canned food throughout the entire shelf life. There is also large amount of toxicological data on epoxy resins. The industry will also keep under close review developments in alternative technologies that deliver an equivalent level of performance and which do not compromise the high degree of microbiological and chemical safety of canned food. However, at present the development of alternative systems that are free of Bisphenol A is very much in its infancy. There is still no technology that provides the same level of protection to the foodstuff as epoxy-based resins. Food and drink manufacturers therefore believe that it would be irresponsible to rush into using alternatives at this stage. Test packing and migration testing is in progress but it is too early to confirm the acceptability of alternatives for the wide range of foodstuffs that are packed into cans.

- *It would be helpful to pool available information on work that is going on overseas on Bisphenol A migration into canned food and drink*

This is being actioned through the can supply industry. In particular the UK industry is liaising with its European and American counterparts in an attempt to collate all the available data on Bisphenol A migration.

- *Which substances are acceptable to environmentalists in this context and on what scientific basis? What information would consumers want about chemical migration from can coatings?*

Since this question is directed at environmental groups we do not feel it appropriate for FDF to respond except to say that we would expect any answer to take account of the outstanding safety record (both in terms of microbiological and chemical safety) that Bisphenol A - based epoxy resins provide and the possible consequences of rushing into changes without fully testing all aspects of any possible alternatives.



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27th June 2001

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Dear Ms Lascelles,

Consultation – Bisphenol A Migration into Canned Foods and Beverages

We refer to Dr David Watson's invitation to comment on the content and implications of the surveillance exercise reported in Food Surveillance Information Sheet no. 13/01 published on 12th April 2001.

We welcome this opportunity to comment on an issue of great significance to the members of our association. We do so via the two enclosed documents – one which is a direct response to the four questions posed and the other which is a general overview of the requirements of a can coating, alternative coating chemistries and current regulatory influences. The whole, we believe, reminds stakeholders of the important rôle played by the can in the preservation and distribution of food and the responsible approach that our industry is taking towards migration issues of public concern.

Should any of the points made in these documents require further explanation, then please do not hesitate to contact me.

Yours sincerely,

David A Smith
Technical Manager

Enclosures:

Food Standards Agency bisphenol A consultation – Responses to the four questions posed.

Food and beverage can internal coatings – An overview.

(Documents package sent unsigned by e-mail and also as signed hard copy)



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FOOD STANDARDS AGENCY BISPHENOL A CONSULTATION – RESPONSES TO THE FOUR QUESTIONS POSED

- ***“What other measures may be needed to reassure consumers?”***

With the exception of the single outlying result of 0.35-0.42 mg/kg, the migration levels of bisphenol A in the FSA survey are consistent with levels found in other industry and independent surveys around the globe (i.e. from non detectable to 0.1 mg/kg food). The outlying result of 0.35-0.42 mg/kg, which is still 7-8 times below the EU migration limit of 3 mg/kg is, from our subsequent investigation, unique to the specific lacquer system that was used for these cans and attributable to a particular bisphenol A-containing cross-linker. This lacquer system does not remain in service, but lacquer systems containing other bisphenol A-containing cross-linkers continue to be used where it has been shown that they do not lead to significant migration of bisphenol A. Consumers should be reassured by the findings of the FSA survey together with the associated opinion of the COT. Consumers would be further reassured by an accurate and balanced media and pressure group reporting of the content of those two documents which demonstrate that current exposure levels from canned food are around 100,000 times below doses that have been found to have an effect in animal studies. Even if all canned food had bisphenol A migration at the level of the single outlying result in the survey, a consumer would need to eat 7 tonnes of canned food each and every day of his or her life to reach this lowest effect level. Notwithstanding the above, industry will continue to work on ways to yet further reduce migration of bisphenol-A as long as this does not in any way prejudice the existing high degree of safety and microbiological integrity of canned food.

- ***“It would be helpful if industry could provide information on progress in this work, for example on possible alternatives to bisphenol A”***

Epoxy and other resins made using bisphenol A are used precisely because they impart to food contact coatings the essential properties which give the best protection of the microbiological and chemical safety of canned food. The challenging requirements of can coatings include in-can sterilisation resistance, long term food product resistance, resistance to tooling and can damage, freedom from taint and low overall migration. Can coatings may only be made using authorised starting materials (referenced to US FDA or other national regulations), and are the result of many years product development and performance testing. As a part of

industry's work to continually improve its products, its suppliers of coatings are researching ways of reducing migration of coating components including bisphenol A, but not at the expense of prejudicing the existing high degree of safety and microbiological integrity of canned food. For epoxy resins in particular, it should be borne in mind that they have an enormous extent of toxicological test data behind them. Any move to a replacement technology which is less toxicologically characterised would be irresponsible and unacceptable to industry. At present, there is not an appropriate technology that would replace bisphenol A-based resins in a substantial majority of can coatings. Migration reduction rather than the elimination of existing technologies is considered the more prudent route.

- ***“It would be helpful to pool available information on work that is going on overseas on bisphenol-A migration in canned food and drink”***

MPMA is liaising with its counterparts globally to identify and make available any other existing bisphenol-A migration data into real foods generated elsewhere. We can already cite however an industry study carried out in USA (Society of the Plastics Industry – Can Coating Migration Study 1995-1996), involving migration testing into a “worst case” food simulant of commercially produced food and beverage cans. Beverage cans gave non-detectable bisphenol A (at 5 µg/kg sensitivity) whilst a range of food cans averaged 37 µg/kg ranging from non-detectable to just over 100 µg/kg – figures of a slightly higher order than those of the FSA survey because of the severity of the food simulant used. These results, plus analysis and discussion, can be viewed at www.bisphenol-a.org/health/exposure/consumer/epoxy/index.html. Based on US dietary patterns, the result is equated to a daily intake for the typical consumer of 0.000105 mg bisphenol A per kg bodyweight per day, which is a quantity 475 times lower than the current EU Tolerable Daily Intake of 0.05 mg/kg bodyweight/day. This EU TDI, in its turn, has a 1000 times safety factor built in when derived from the lowest observed adverse effect level by expert consensus.

- ***“Which substances are acceptable to environmentalists in this context and on what scientific basis? What information would consumers welcome about chemical migration from can coatings?”***

We leave this answer to the environmentalists and consumer representatives. However, we would expect that in answering this question, such organisations would take account of the overall provision of a safe and wholesome food supply and the essential part that canned food plays in this. As we have stated elsewhere, it is essential that a desire to move away from tried and tested existing technologies does not result in a move to materials or technologies about which less is known and which could possibly prejudice the existing high degree of safety and microbiological integrity of canned food.

Attached at Appendix 1 is CEFIC Bisphenol A Sector Group's June press release on bisphenol A calling for a scientific approach towards the future regulation of bisphenol A.

BISPHENOL A SECTOR GROUP

A SECTOR GROUP  OF

Industry Calls for Conclusions to be based on the Weight of Scientific Evidence

TMII 2001 - Human Health Risk Assessment for Bisphenol A

Brussels, 7 June 2001– Industry supports the full and thorough scientific review of all available evidence on Bisphenol A (BPA) and demands that the Risk Assessment on BPA be based on the weight of scientific evidence, examining both hazard and exposure to determine risk. Any other approach would establish a dangerous precedent, undermining the fundamental pillars of the Risk Assessment process and creating the potential for abuse of public policy and uncertainty for the regulator and the regulated, as well as consumers.

Industry endorses the conclusions in the current draft Risk Assessment report (May 2001) on the risk characterisation with respect to human health effects of BPA, as they are based on the weight of scientific evidence. However, industry strongly opposes any conclusion that is not based on validated testing methods and protocols, recognised risk assessment practices of assessing hazard and exposure and statistically powerful studies employing Good Laboratory Practices (GLP). Furthermore, industry opposes the classification for reprotoxic effects (R60), as the weight of scientific evidence does not support this proposed classification.

The UK rapporteur's proposal for the classification of BPA for reproductive effects (R60) is based primarily on the mouse continuous breeding study (U.S. NTP, 1985). Evidence in the study report clearly shows that reduction of litter size and number of live pups per litter are non-specific and secondary to maternal toxicity. The Research Triangle Institute study of 3 maternal and 4 offspring generations (multi-generation reproductive study on rats, 2000) demonstrated that reproductive effects are seen only in conjunction with maternal toxicity. When examined closely, these studies unequivocally confirm the conclusion that classification as R60 is not justified because oral doses of BPA below those producing systemic toxicity do not cause any oestrogen-like or reproductive effects even when administered during sensitive life stages in either sex.

As recognised in the draft Risk Assessment, seven statistically powerful studies, including a 2-generation study and a 3-generation study conducted under GLP, have demonstrated that BPA has no adverse effects on development at low dose levels. Studies claiming such a low dose effect rely on a small number of animals, non-validated endpoints, and experimental protocols and have never been replicated or confirmed in any rigorously controlled study conducted under regulatory approved protocol.

The recent report by an independent panel of experts established by the U.S. National Toxicology Program (May 2001) supports the conclusion that no developmental effects from BPA have been demonstrated

“There is credible evidence that low doses of BPA can cause effects on specific endpoints. However, due to the inability of other credible studies in several different laboratories to observe low dose effects of BPA, and the consistency of these negative studies, the Subpanel is not persuaded that a low dose effect of BPA has been conclusively established as a general or reproducible finding. In addition, for those studies in which low dose effects have been observed, the mechanism(s) is uncertain (i.e., hormone related or otherwise) and the biological relevance is unclear.”(National Toxicology Program’s Report of the Endocrine Disruptors Low Dose Peer Review, page 1-11)

The U.S. Food and Drug Administration, the European Union’s Scientific Committee for Foods, the Japanese Ministry of Health and other international regulatory agencies have all concluded that BPA poses no risk to human health at any realistic level of exposure.

BPA is an essential building block for the manufacture of polycarbonate plastics as well as epoxy resins used in coatings. It is vital to the production of plastic products such as safety equipment, consumer goods such as food and beverage containers, audio-compact discs, CD-ROMs and DVDs and vital medical devices (e.g. over 120,000 patients throughout Europe depend on its use in dialysis machines). Safely used for over forty years, BPA is one of the most extensively studied chemicals. The comprehensive safety research on BPA demonstrates that consumer products made with BPA are safe for their intended uses and that BPA poses no risk to human health at any realistic level of exposure.

The CEFIC BPA Sector Group supports the full and thorough scientific review of all the available evidence on BPA through the EU risk assessment process. We are committed to transparency and rigorous procedures and have co-operated fully with the UK rapporteur. We hope that others will similarly base their views on sound science and objective analysis.

Further information on Bisphenol A can be found at: <http://www.bisphenol-a.org>

Further information can be obtained from:

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Food and Beverage Can Internal Coatings – An Overview

Introduction

The canning, in-can processing, distribution and storage of foodstuffs have been a major benefit to mankind for nearly two centuries. It has played a vital role in ensuring a wholesome, nutritious and safe, year-long food supply, and without it, the world's incidence of food spoilage and wastage would have been substantially higher.

Throughout this period, the can itself has undergone numerous step changes in image, structure, performance and, of course, manufacturing technologies. As the can has evolved, so has the range of food and beverages that are packed in cans, and also the technology of canning. This has led to the increasing need to use a high performance internal protective coating to avoid the food attacking the metal of the can and so leading to a degradation of food quality and the possibility of microbiological infection of the can contents through loss of can integrity.

The fundamental basis of food canning is that food is filled into the can which is then hermetically sealed. The can then undergoes a heat process (typically 121°C for an hour) which cooks the food and sterilises it. Once sterilised, the high degree of physical integrity of the can prevents any microbial or chemical recontamination which ensures a long and extremely safe food product throughout its shelf life (up to 5 years). The selection of the right protective coating is essential to retain the can's physical integrity and thus the safety and quality of canned food over this shelf life.

Whilst canned beverages do not need the sterilisation process to ensure microbiological sterility, the integrity of the can is still essential to protect the beverage from contamination which could lead to spoilage of the contents.

Basic Criteria for Coating Selection

Firstly, coatings are only formulated using monomers, other starting substances and additives permitted by appropriate food contact regulations. Most usually, because of the global nature of the trade in canned food and the absence of harmonised EU legislation applicable to coated metal packaging, coatings are formulated to US FDA

(Food & Drug Administration) regulations. This approach of selection of starting components only from a permitted list coupled with an overall migration limit, has safely and satisfactorily protected consumers for many decades.

In addition to these compositional and migration constraints, the coating must protect the metal from attack by the foodstuff during filling, sterilisation, and storage in order to retain the integrity and safety of the can. This fundamental requirement further limits the choice of starting materials and finished coating chemistries to those that can actually perform this task. Although accelerated test procedures can be used to an extent to evaluate new coatings, there is no adequate alternative to long term pack testing for validating the performance of the coating.

Overall, the process of development and testing of a new can coating typically takes many years if formulated only from existing permitted starting substances, and many years more if new starting substances need to be identified, and toxicologically tested. Inevitably such developments bring with them the possibility of performance failure with the associated risk of compromising the unrivalled microbiological safety of canned food. In addition, changes in coating technologies will usually lead to reliance on starting substances about which less is known toxicologically. It is for these reasons that industry resists any move away from existing coating technologies unless there are valid demonstrable reasons for such a change giving an overall increase in consumer safety. To make such a move without such a justification would be neither prudent nor responsible.

Internal Food Contact Coating Types and Their Uses

Table 1 (attached) highlights the six main internal coating chemistries, their principal uses and a summary of their flexibility (indicative of their suitability for extreme metal deformation) and resistance to food products and product processing.

Within one can, different coating types are often used to protect the can body, the welded body side seam, easy open end and non easy open end in order to ensure that the optimum protection is given to each component. Even for a single component, coatings can be, and frequently are, used in combination to benefit from the desirable properties of each. An example of this would be the use on metal closures of an internal system of epoxy phenolic sizecoat under an organosol topcoat, the former providing good substrate adhesion and flexibility in addition to product resistance, and the latter giving ultimate flexibility, product resistance and adhesive compatibility with the gasket lining compound which provides the seal to the glass jar.

A minor proportion of cans, primarily for acidic fruits, have protective coatings on the ends but not on the body. This method of packing is not, however, an option for the large majority of food products, and is never possible for beverages.

Present and Future Food Contact Regulation of Canned Food and Beverages

Clearly, it is important that all food contact materials and articles are subject to regulation in order to protect the consumer. As explained above, in the absence of harmonised EU legislation relevant to coated metal packaging, and because of the global market for canned food, it is the US FDA regulations that are most usually used to demonstrate the safety of can coating systems.

The EU 'Framework' Directive 89/109/EC opened the path over time for separate specific food contact Directives, including one for coatings. The first to be enacted was the 'Plastics' Directive 90/128/EEC which has, to date, undergone five amendments with a sixth imminent. The general principle is to control the migration of residual starting substances (which must themselves be positively listed), and also to have an overall migration limit. This "positive list" principle is similar to that of US FDA and indeed the great majority of other food contact legislation. An EU Directive specific to coatings still seems a long way off although the Council of Europe is separately developing a 'Coatings Resolution' which may influence the ultimate EU Directive. It is not yet clear whether the tried and tested "positive list" principle will continue to be used in this Resolution, though the logic and reason for not basing the Resolution on this principle has yet to be demonstrated.

In the meantime, aspects of the Plastics Directive are becoming influential, and some coating constituents are being regulated on a specific basis (e.g. the forthcoming "Epoxy" Directive"). Some member and non-member states are applying Directive 90/128/EEC in full to coatings, although this can lead to problems as this Directive was developed specifically for packaging made entirely out of plastics. The can manufacturing industry and its suppliers are working with European and national member state bodies to assist in the development of harmonised legislation specific to coated metal food and beverage packaging which must have the prime aim of protecting the consumer. However, it is essential that any new legislation should not in any way prejudice the existing unrivalled microbiological safety record of canned food by forcing changes away from existing proven coatings systems to newer systems unless there are good consumer safety reasons for doing so.

Conclusions

Canned food and beverage offers the best combination of microbiological safety, protection from contamination and long shelf life. This is, in no small part due to the use of tried and tested high performance protective coatings formulated in compliance with regulations, and subject to rigorous performance testing and approval. The selection of the correct coating for each application is subject to many constraints, giving very limited choice. Any change in coating technology carries with it a risk of performance failure and possible microbiological contamination. For this reason, industry is resistant to change unless there is an overall demonstrable consumer safety benefit in that change – even then, changes can only be made after proper performance evaluation.

However, the can manufacturing industry and its suppliers continue to research coating technology as a part of our commitment to continuous improvement, but will always guard against any reduction in overall safety or integrity of our products. We also continue to work with European and national bodies towards harmonised EU legislation for coated metal packaging that is both workable, and focussed on overall consumer protection.

TABLE 1 – Different Types of Food Contact Coating Chemistries

RESIN SYSTEM	Description	Main Uses	Typical Packed Products	Flexibility	Pack Resistance
EPOXY PHENOLIC	High molecular weight epoxy resins cross-linked with phenolic resins	<ul style="list-style-type: none"> - Universal gold lacquer for 3 piece cans/ends - Shallow drawn cans 	<ul style="list-style-type: none"> - Non aggressive/medium aggressive products. - Vegetables, meat, fish, soups, tomatoes, fruits 	Good	Very Good
ORGANOSOL	PVC dispersed in thermosetting binder solution.	<ul style="list-style-type: none"> - Deep drawn cans - Easy Open ends - Metal closures (Often used over epoxy phenolic basecoat) 	<ul style="list-style-type: none"> - Aggressive products - Pickled foods, ready meals, some fruits 	Very Good	Very Good
EPOXY ANHYDRIDE	High molecular weight epoxy cross-linked with anhydride hardeners	<ul style="list-style-type: none"> - Internal white (pigmented with TiO₂) for 3-piece cans 	<ul style="list-style-type: none"> - Non aggressive products - Vegetables, some meats 	Good	Good

EPOXY AMINO	High molecular weight epoxy cross-linked with amino resins.	- Limited food systems (particularly dry foods)	- Powdered beverages - Also used as clear external on ends (incl. EOE)	Good	Limited
EPOXY ACRYLATE	Water-dispersible resin system, water white. Can be cross-linked with phenolic resins for improved product resistance	- Universally used as the internal spray liner for 2-piece beverage cans	- Beer & soft drinks - Isotonic drinks - Hot-serve beverages - Some food cans	Good	Limited
POLYESTER	Polyester resins cross-linked with amino or phenolic resins	- Non aggressive foods	- Peas, sweet corn	Very Good	Limited

Date: 27 June 2001
Ref: 01F076
HLW/FSA

Harriette Lascelles
Food Standards Agency
Food Contact Materials Unit
515C
Aviation House
125 Kingsway
London WC2B 6IH

Dear Harriette Lascelles

**BCF response to the FSA consultation:
Migration of bisphenol A from can coatings into food**

We thank you for the opportunity to comment on the consultation following the presentation of the FSA findings on the migration of bisphenol A from can coatings into food, on the 12th April. We give below some background and answers to the questions raised and hope that these are of help to you.

The can coatings used as protective liners in food and beverage cans are inert materials that have a proven record over more than 40 years of providing a safe and effective means of maintaining the quality and integrity of canned foods and drinks. Bisphenol A (BPA) is a key building block of components used in the majority of can coatings. These protective coatings are used because they produce water-white and flexible coatings that are resistant to the foods and drinks that they come into contact with and are also capable of withstanding the high temperature conditions that exist during the in-can sterilisation of foods.

Research, including the recent FSA survey (Food Surveillance Information Sheet No 13/01, April 2001) has shown that under certain conditions trace amounts of bisphenol A have been detected in some canned foods. However, the resulting dietary intake, even under the most conservative, worst case, exposure considerations, is many orders of magnitude lower than the Tolerable Daily Intake (TDI) established by the SCF of 0.05 mg/kg/day. The SCF is expected to review the TDI for Bisphenol A during 2001 and, taking all relevant new data into account, will determine if the current NOEC (No Observed Effect Concentration) of 50 mg/kg/day which is the basis of the current TDI is still applicable or needs to be revised.

Furthermore the most comprehensive study to date on consumer exposure to BPA is currently being conducted by the UK Health and Safety Executive (HSE) on behalf of the European Commission. The current draft risk assessment report, which uses very conservative exposure estimates, concludes that there is no cause for concern regarding consumer exposure. In evaluating the hazards of bisphenol A the HSE has taken into account all the recent toxicology publications on BPA.

Consequently, we believe that the weight of scientific evidence supports the position that human exposure to Bisphenol A from can coatings is minimal and poses no known health risks.

We give below responses to the specific questions raised by the Agency.

"The survey was carried out to establish whether migration of bisphenols A or F occurs into retail samples of canned foods in the UK. No migration of bisphenol F was found. Bisphenol A was detected at up to 0.07 mg/kg in 37 samples and at 0.35 to 0.42 mg/kg in one sample (limit of detection: 0.002 mg/kg; limit of quantification: 0.007 mg/kg). Bisphenol A is used to make most types of epoxy resins. These are cross-linked before being applied to the inside of cans. Bisphenol A is not generally used for cross-linking as this could lead to more migration. We understand that action has been taken to avoid the use of this substance as a cross-linking agent in can coatings. *What other measures may be needed to reassure consumers?*"

We can confirm that bisphenol A is not used as a cross-linker in epoxy resins, however it is used as a starting component in the production of reactive phenol/formaldehyde resins. These are used, and have been for many years, as cross-linkers for epoxy resins to provide coatings with excellent dry film properties easily meeting the regulatory limits for BPA.

We believe that consumers can be reassured about the safety of canned foods and drinks and we agree with, and welcome, the conclusions of the Committee on Toxicity (COT) that on present evidence the levels of BPA identified in canned foods analysed in the FSA survey are unlikely to be of any concern to health. We also agree that there is no reason for consumers to change their source of foodstuffs as a result of these findings. Furthermore the bisphenol A industry has and is continuing to conduct extensive research to address the uncertainties referred to by the COT in the scientific understanding of the potential endocrine effects of BPA. However, we believe that the overwhelming weight of evidence is that BPA does not cause adverse effects at low dose exposures. In this regard we would bring to your attention the recently published conclusions of the USA EPA Low Dose Panel review of BPA. The Panel concluded as follows: -

"There is credible evidence that low doses of BPA can cause effects on specific endpoints. However, due to the inability of other credible studies in several different laboratories to observe low dose effects of BPA, and the consistency of these negative studies, the Subpanel is not persuaded that a low dose effect of BPA has been conclusively established as a general or reproducible finding. In addition, for those studies in which low dose effects have been observed, the mechanism(s) is uncertain (i.e., hormone related or otherwise) and the biological relevance is unclear."

In the general debate on consumer exposure to oestrogens it is also important to put the issue of exposure to so called chemical oestrogens into perspective as many foods, including a large number of fruits, vegetables and soya,

contain very much higher levels of naturally occurring phytoestrogens. However, there is no suggestion that eating these foods is harmful. On the contrary a diet rich in such foods is generally believed to be healthy.

"UK industry has been taking steps to find ways of reducing the migration of bisphenol A and to find possible alternative substances. Given the role that coatings have in protecting the microbiological and chemical safety of canned food, it is important that any alternative substances to bisphenol A do not allow bacterial or metallic contamination of canned food and do not themselves raise safety concerns. *It would be helpful if industry could provide information on progress in this work, for example on possible alternatives to bisphenol A.*"

Can coating manufacturers are continuing to develop new coating technologies to support the technical, commercial and market needs of their customers. Some of these technologies are not based on bisphenol A derived materials. The full range of properties afforded by bisphenol A derived technologies may prove difficult, if not impossible, to duplicate. Currently replacement technology does not exist to cover all the needs of the industry, for example replacing epoxy with polyester does not provide the necessary barrier properties for highly acidic products such as tomato-based sauces etc.

Where alternative technologies are available or are developed they still have to meet all the stringent health, safety, quality and performance standards of bisphenol A derived technologies as well as achieving the required levels of regulatory compliance and approvals.

The promotion of any alternative technology should be based on the merits of the product and not be driven by raising unnecessary and unfounded fears on the safety of bisphenol A derived products. For the food contact coatings industry the safety of our customers and consumers is paramount. We will continue to closely monitor scientific developments and the outcome of the risk assessment and the SCF deliberations, both of which will have Europe-wide implications. The industry will take appropriate actions to ensure we continue to supply products that provide a safe and effective means of maintaining the quality of canned foods and beverages.

"The trade in canned foods is international. But there appears to be little information about bisphenol A migration into canned food and drink in other countries. The Food Standards Agency will continue to press for EU-wide controls on chemical migration into canned foods (see for example Food Surveillance Information Sheet no. 7/00). *It would be helpful to pool available information on work that is going on overseas on bisphenol A migration into canned food and drink.*"

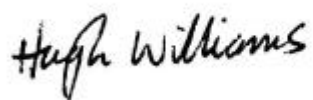
There have been a number of published studies on bisphenol A into foods or food simulants. The most useful sources of information are the bisphenol A website, maintained by the BPA Global Industry Group, (<http://www.bisphenol->

[a.org](#)) and the comprehensive literature referenced in the draft Risk Assessment Report on bisphenol A written by the UK HSE.

"Some environmentalists have pressed for more information on the use of substances such as bisphenol A, that they believe are hazardous, to allow consumers to make an informed choice. *Which substances are acceptable to environmentalists in this context and on what scientific basis? What information would consumers welcome about chemicals migration from can coatings?*"

It is to be hoped that whatever the conclusions of the EU risk assessment on bisphenol A and the deliberation of the EU SCF, that the environmentalists accept the results of these scientific studies and act accordingly and responsibly. The alarmist methods, terminology and images some environmentalists have used to raise issues in the media are not helpful in enabling consumers to make informed choices. Consumers need balanced information and not one-sided scare stories to order to make an informed judgement, and to this end it should again be stressed that canned food has a 40+ year history of supplying food safely to the consumer.

Yours sincerely

A handwritten signature in black ink that reads "Hugh Williams". The signature is written in a cursive, slightly slanted style.

Hugh Williams
Technical Manager

e-mail from Mark Wood, Promotion & Marketing Manager, G & G Food Supplies Ltd., Vitality House, 2-3 Imberhorne Way, East Grinstead, West Sussex RH19 1RL:

"Mark Wood" promotion@gandgvitamins.com on 22/05/2001

To: Harriette Lascelles/CST/FSA

Subject: Consultation: Migration of Bisphenol A from Can Coatings into Food

I have a couple of questions which I hope will be considered:

1. Is the migration of Bisphenol A accelerated if a can is dented or damaged in some way? Many shops sell dented cans at reduced prices, therefore consumers are purchasing and consuming the contents.
2. Does long-term storage in the can have an effect on Bisphenol A levels? Many consumers buy 'store cupboard' items and stash them for later use, this is particularly prevalent with the many 'Buy 2 Get 1 Free' type offers. Canned goods can be stored for use for years before use.
3. Does heating or chilling a can affect the Bisphenol A levels? Whilst it is prudent not to, some consumers store half-full open cans in the fridge and some canned food can be cooked 'in the can' in the oven.
4. This probably isn't your domain, but it is relevant none the less; what is the effect on household pets eating canned food?

Mark